REMARKS

Claims 1 and 6-41 are pending in the present Application, claims 2-5, 16-17 and 21 have been canceled, claims 1, 10 and 40-41 have been amended, and no claims no have been added, claims 11, 13, 15, 18-20, 22-27 and 30 and 32-34 have been withdrawn from consideration, leaving Claims 1, 6-10, 12, 14 and 28-29, 31 and 35-41 for consideration upon entry of the present Amendment.

Applicant's acknowledge the Examiner's additional withdrawal of claims 20, 22-23 and 25-27 under 37 CFR 1.42(b), as being drawn to nonelected species. (Office Action dated 7/29/2008, page 1)

In the Office Action, the Examiner stated that claims 11, 13, 15, 18-20, 22-27, 30 and 32-34 have been withdrawn from consideration. Applicants note that in the Response filed on April 24, claims 11, 13, 15, 18, 19, 24 and 30-41 were withdrawn from consideration. However, upon review, Applicants agree with the Examiner that claims 31 and 35-41 should not have been withdrawn.

Claims 1, 10 and 40-41 have been amended to better define the invention.

Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Restriction/Election

In the pending Office Action, the Examiner acknowledged Applicants election with traverse of cryptotanshinone and tanshinone IIA for species A, 1β-hydroxycryptotanshinone for species B and obesity for species C. (Office Action dated 7/29/2009, page 2) Further, the Examiner considered Applicants grounds for traversal, but found these arguments unpersuasive. (Office Action dated 7/29/2009, page 2) In particular, the Examiner stated:

> The traversal is on the ground(s) that the composition claimed in claim 1 is distinguisahable over the prior art due to the presence of synergism as shown in the specification. This is not found persuasive because applicant's claim for unexpected results based on synergism is not sufficient to overcome the anticipatory references discussed below. The elected composition is not considered allowable. Furthermore, the anticipatory references discussed below also demonstrate the lack of unity between the different compositions claimed in claim 1 because the references anticipate the elected species and do not

necessarily anticipate the other compositions encompassed by the claims. (Office Action dated 7/29/2008, page 2) Applicants respectfully traverse this rejection because, as discussed in detail below, Claim 1 as amended in not anticipated by the references cited. Further, Applicants note that the arguments presented regarding the synergistic effect of the claimed composition were presented in relation to the restriction requirement, not to overcome a rejection under 35 U.S.C. § 102.

Applicants maintain that claim 1 recites that the distinguishable feature of the present invention is directed to a mixture (composition) comprising cryptotanshinone and tanshinone IIA; and further comprising one or more compounds selected from the group consisting of tanshinone I, 15,16 dihydrotanshinone I. Such a mixture shows a significant synergistic effect, which is supported by the specification at page 14, lines 6-12 and Figures 17-19 showing the experimental results. For convenience, Applicants have reproduced page 14, lines 6-12 of the Specification below.

> More surprisingly, the present inventors have confirmed that enhancement effects of cryptotanshinone, tanshinone IIA, tanshinone I and 15,16-dihydrotanshinone I on AMPK activity is significantly increased by combinational use of two or more of these compounds. Such a significant synergistic effect was not totally predicted and it was also confirmed that such effect was exhibited, regardless of kinds of those four tanshinone derivatives. Therefore, among combinations of the above-mentioned compositions, compositions (v) through (viii) are particularly preferred.

Accordingly, Applicants respectfully submit that the present invention must be understood to be directed to composition comprising cryptotanshinone and tanshinone IIA; and further comprising one or more compounds selected from the group consisting of tanshinone I, 15,16 dihydrotanshinone I. For this reason at least, Applicants traverse the Election/Restriction requirement.

Claim Objections

Claims 16 and 17 have been objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. (Office Action dated July 29, 2008, page 3) Claims 16 and 17 have been cancelled, rendering this objection moot. Applicants respectfully request a withdrawal of the objection.

Claim 10 has been objected to for the following informalities: "therebetween" should properly be "there between". (Office Action dated July 29, 2008, page 3) Claim 10 has been amended to recite "The composition as set forth in claim 1, wherein the ratio between cryptotanshinone and tanshinone IIA is in the range of 1:5 to 5:1 (w/w)." Applicants believe that this amendment to claim 10 overcomes the Examiners objection. Applicants respectfully request a withdrawal of the objection.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 6-10, 12, 14, 16, 17, 21, 28, 29, 31 and 35-39 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. (Office Action dated 7/29/2008, page 4) In particular, the Examiner stated that the specification, while being enabling for reducing obesity, does not reasonably provide enablement for preventing obesity. (Office Action dated 7/29/2008, page 4) Applicants respectfully traverse this rejection.

Claim 1 has been amended to delete the term "preventing". Thus, as amended, claim 1 is directed to "a composition for treating obesity and metabolic syndrome diseases." Applicants believe that this amendment places claims 1, 6-10, 12, 14, 21, 28, 29, 31 and 35-39 in compliance with 35 U.S.C. § 112, first paragraph. Claims 16 and 17 have been cancelled. Applicants respectfully request a withdrawal of the rejection and an allowance of the claims.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 16, 17, 40 and 41 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action dated 7/29/2008, page 5) Applicants respectfully traverse this rejection.

Claims 16 and 17 have been cancelled, rendering the rejection of claims 16 and 17 moot. Applicants respectfully request a withdrawal of the objection.

With regard to claim 40, the Examiner stated the use of the parentheses around

"vacuum" renders the claim indefinite. (Office Action dated 7/29/2008, page 5) Claim 40 has been amended to delete the parentheses around "vacuum".

With regard to claim 41, the Examiner stated that it is unclear what characteristics the Danshen must have in order to be considered "drug material" and "raw drug material". (Office Action dated 7/29/2008, page 5) Claim 41 has been amended to clarify that the Danshen extract is a dried material or raw material.

Applicants believe the amendments to claims 40 and 41 discussed above place these claims in compliance with the requirements of 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1, 7-10, 16, 17, 21, 28, 29, 31, 35, 37, and 39 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Sucher (US 2002/0077352) ("Sucher"). (Office Action dated 7/29/2008, page 5) Applicants respectfully traverse this rejection.

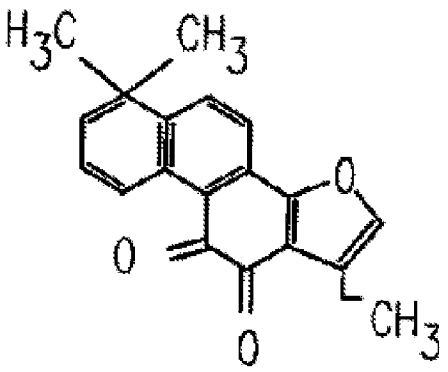
To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Varient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987).

As amended, independent claim 1 recites:

> 1. A composition for treating obesity and metabolic syndrome diseases, comprising a therapeutically and/or prophylactically effective amount of Danshen *(Salvia miltiorrhiza)* extract
> wherein the Danshen extract comprises cryptotanshinone and tanshinone IIA;
> and further comprising one or more compounds selected from the group consisting of tanshinone I and l5,16-dihydrotanshinone I,
> wherein the composition is used for treating obesity and metabolic syndrome diseases.

To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Varient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987).

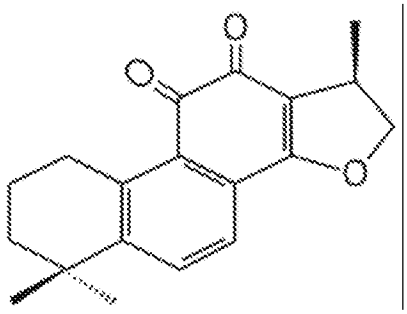
Sucher is related to pharmacological blockade of excessive activation of N-methyl-D-asparate receptor (NMDARs) and reduction of ischemic injury of neurons. Sucher discloses the compound represented by the below chemical structure as "Cryptotanshinone."



Cryptotanshinone

III

(Structure III, Figure 1C; paragraph 19) However, the cryptotanshinone compound disclosed by Sucher is structurally different from the cryptotanshinone compound defined in the present invention. For convenience, the cryptotanshinone compound disclosed by the instant disclosure is reproduced below.



Cryptotanshione

([Formula 2], page 11, lines 5-10) Thus, Sucher discloses "cryptotanshinone III" but fails to disclose "cryptotanshinone."

Since Sucher does not discloses Cryptotanshinone as presently claimed, Sucher does not teach all elements the claimed invention. Therefore, Applicants respectfully assert Sucher does not anticipate that claim 1. Claims 7-10, 21, 28, 29, 31, 35, 37, and 39 depend from claim 1 and include all the limitations thereof. Claims 16 and 17 gave been cancelled. Applicants respectfully request a withdrawal of the rejection and an allowance of the claims.

Claims 1, 7, 14, 16, 17, 21, 28, 29 and 31 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Tezuka (Chem. Pharm. Bull. (1997), vol. 45, no. 8, pp. 1306-1311) ("Tezuka"). (Office Action dated 7/29/2008, page 6) Applicants respectfully traverse this rejection.

Tezuka relates to the constituents of an MeOH extract of Salvia miltiorrhiza BUNGE, which showed strong aldose reductase (AR) inhibitory activity. According to Tezuka, two new abeitane-type diterpenoid compounds, danshenol A and danshenol B, were isolated. Tezuka further discloses that danshenol A and danshenol B were isolated together with known tanshinone compounds.

Tezuka discloses that the tanshinone compounds were isolated with the following composition: cryptotanshinone 0.010%, tanshinone IIA 0.13%, tanshinone I 0.0046% and dihydrotanshinone 0.0035%. However, Tezuka fails to teach or suggest that the combination of two or more compounds as claimed. Applicants submit that the synergistic effect the combination of two or more compounds as claimed on AMPK activity and thus, for treating obesity and metabolic disease syndrome is not taught in the prior art. Since the synergistic effect cannot be expected when two or more compounds are mixed, Applicants believe that Tezuka does not anticipate the composition as claimed. Thus, Applicants respectfully assert Tezuka does not anticipate that claim 1. Applicants respectfully request a withdrawal of the rejection and an allowance of the claims.

Claims 1, 16, 17, 21, 28, 29, 31, 35, 37 and 39-41 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Wei (US 6541046) ("Wei"). (Office Action dated 7/29/2008, page 7) Applicants respectfully traverse this rejection.

Wei discloses a composition comprising a decoction of rhubarb root and stem in combination with other compounds or compositions, such as astragalus root, red sage root, turmeric and dried ginger, to enhance the tolerance of rhubarb and increase the efficacy and safety of a formulation derived from a rhubarb-containing decoction. (Col. 5, lines 51-59) Further, referring to column 9, lines 14-17, the red sage root enhances the function of cardiovascular system and counter-balances a common side effect of many weight loss drugs,

i.e., an increase risk of heart stress that can lead to actual tissue damage. Thus, Applicants assert that the Danshen extract disclosed by Wei is just supplemental to the rhubarb root composition and merely used to address the problems associated with the natural herbal extracts and D3 does not teach that Danshen extract is effective for weight loss. Further, Applicants note that the main components in an extract used for such supplement are not the same as those in the claimed composition. For these reasons, Applicants believe Wei does not anticipate the instant claims.

With regard to claims 40-41, Wei discloses filtering and straining herbal extracts by conventional methods, including using multi-layered medium filter paper, filter press, centrifuge cloth-lined sieve or cheesecloth. (Col. 10, lines 46-49) Wei discloses that the filtered liquid extract may be directly administered orally (i.e., without any further processing). (Col. 10, lines 49-52) Alternatively, Wei discloses concentrating the liquid extract by evaporation using a rotary evaporation flask. (Col. 10, lines 53-59) Thus, Wei does not disclose a method for preparing a Danshen extract comprising filtering the crude extracts, followed by vacuum concentration. Therefore, Wei does not teach all elements of claims 40-41.

In summary, applicants respectfully assert that Wei does not anticipate the instant claims under § 102(b). Applicants respectfully request a withdrawal of the rejection and an allowance of the claims.

Claims 1, 16, 17, 21, 28, 29, 31 and 35-41 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Tashiro (US 5589182) ("Tashiro"). (Office Action dated 7/29/2008, page 8) Applicants respectfully traverse this rejection.

Tashiro is generally directed to a pharmaceutical composition suitable for the treatment cardiovascular diseases, Alzheimer's disease, depression and other conditions. Applicants respectfully assert that Tashiro does not teach a composition as claimed. Specifically, Tashiro is not directed to a pharmaceutical compositions comprising mainly Danshen (Salvia miltiorrhiza) extract. Rather, the composition disclosed by Tashiro contains the extracts from various Chinese plants and herbs. Specifically, the composition disclosed by Tashiro contains

"TP-93-U" and Table 1 identifies more than 20 components and that "TP-93-PII" contains at least four components. Accordingly, Applicants believe that the composition disclosed by Tashiro is not the same as the instantly claimed composition.

Applicants respectfully assert Tashiro does not anticipate that claim 1. Claims 21, 28, 29, 31 and 35-39 depend from claim 1 and include all the limitations thereof. Claims 16 and 17 gave been cancelled.

With regard to claims 40-41, Tashiro discloses that the extract is made by extracting the plant material with water, filtering the extract and concentrating the extract. (Col. 7, lines 50-60 and Col. 8, lines 7-10) Tashiro does not disclose a method for preparing a Danshen extract comprising filtering the crude extracts, followed by vacuum concentration. Therefore, Tashiro does not teach all elements of claims 40-41.

In summary, applicants respectfully assert that Tashiro does not anticipate the instant claims under § 102(b). Applicants respectfully request a withdrawal of the rejection and an allowance of the claims.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1, 7-10, 14 and 35-39 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Sucher. (Office Action dated 7/29/2008, page 9) Applicants respectfully traverse this rejection.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, or knowledge generally available in the art at the time of the invention, must provide some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). As noted above, Sucher does not discloses Cryptotanshinone as presently claimed, Sucher does not teach all elements the claimed invention. Since Sucher does not teach all elements the claimed invention, Applicants believe that a *prima facie* case of obviousness has not been made. Claims 7-10, 14 and 35-39 depend from claim 1 and include all the limitations thereof. Applicants respectfully request a withdrawal of the rejection and an allowance of the claims.

Claims 1, 6, 16, 17, 21, 28, 29, 31, 35 and 39 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Sairafianpour (J. Nat. Prod. (2001), vol. 63, pp. 1398-1403)("Siarafianpour") in view of Yuan (CN 1264580) ("Yuan"). (Office Action dated 7/29/2008, page 11) In making the rejection, the Examiner stated that Sairafianpour teaches the pharmaceutical effects of both cryptotanshinone and 1-beta-hydryxycryptotanshinone and that both of these compounds function against human carcinoma. (Office Action dated 7/29/2008, page 11) Yuan is cited for teaching the use of tanshinone IIA to treat human carcinomas. (Office Action dated 7/29/2008, page 11) Applicants respectfully traverse this rejection.

Claim 1 has been amended to include the functional limitation "wherein the composition is used for treating obesity and metabolic syndrome diseases." As noted in the specification, metabolic syndrome diseases generally refer to syndromes involving health risk factors such as hypertriglyceridemia, hypertension, glycometabolism disorder, blood coagulation disorder and obesity. (page 1, lines 16-18) Both Sairafianpour and Yuan are cited for disclosing the use of cryptotanshinone and/or tanshinone for treat carcinomas. These references do not disclose a composition for treating obesity and metabolic syndrome diseases, comprising a therapeutically and/or prophylactically effective amount of Danshen *(Salvia miltiorrhiza)* extract, wherein the composition is used for treating obesity and metabolic syndrome diseases.

Even if a prima facie case of obviousness were conceded, which it is not, an applicant can rebut a prima facie case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1987, 1901 (Fed. Cir. 1990). The Examiner uses the term "additive results" in rejecting the present invention under 35 U.S.C. § 103. Also, the Examiner alleges that the results shown in the specification are not considered to show that the specific amount of the ingredient itself produces unexpected synergistic results rather than expected additive results. Applicants maintain that a composition of two or more compounds from the specific compounds identified in claim 1

shows a significant synergistic effect, which is supported by the Specification at page 14, lines 6-12 and Figures 17-19 showing the experimental results. In the pending Office Action, the Examiner alleges that the results shown in the specification are not considered to show that the specific amount of the ingredient itself produces unexpected synergistic results rather than expected additive results. (Office Action dated 7/29/2008, page 10) Applicants respectfully disagree. The present specification shows clearly on page 14, lines 6-12 and Figures 17-19 the fact that the combination of specific components among Danshen (Salvia miltiorrhiza) extract provides a significant synergistic effect. Such synergistic effect goes beyond the expected "additive result".

Further, the Examiner also alleges that even if unexpected results were seen, they would not be commensurate in scope with all of the ratios encompassed by the claims. (Office Action dated 7/29/2008, page 10) However, Applicants respectfully assert that the experimental results of the present specification ascertain sufficiently the synergistic effect in the wide range of the ratios.

In summary, Applicants believe that the combination of Sairafianpour and Yuan do not teach all elements of the claimed invention, and that the claimed composition produces unexpected synergistic results. For these reasons at least, Applicants believe that a *prima facie* case of obviousness has not been made. Applicants respectfully request a withdrawal of the rejection and an allowance of the claims.

Conclusion

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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